

REMARKS

Claims 5-10 are in the application. With the filing of this response, Claims 5, 7, and 8 have been cancelled. Claims 6, 9, and 10 remain in the application.

I. The Examiner has rejected Claims 5-10 under 35 USC 103(a) as being unpatentable over Jerussi *et al.* (WO 00/51546) in view of Morgan *et al.* (US 6,274,579). It is the position of the Examiner that there would have been a reasonable expectation of successfully treating anxiety disorders in humans with (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol because the effectiveness of hydroxybupropion metabolites in treatment of anxiety disorders is well known by Jerussi *et al.* and because (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol is the most active hydroxybupropion as reported in Morgan *et al.* (US 6,274,579).

Applicant's argument for this rejection is as follows.

As amended, the application contains Claims 6, 9, and 10. Claim 6 relates to the treatment of "mixed anxiety-depressive disorder" as defined in the instant specification at paragraph [0020]. The Jerussi *et al.* document is silent with respect to the treatment of applicant's claimed "mixed anxiety-depressive disorder". Jerussi *et al.* disclose all manner of bupropion metabolites for a myriad of treatments. Morgan *et al.* (US 6,274,579) is also silent with respect to the treatment of anxiety. Therefore, this combination of the references does not teach or suggest Applicant's claimed method of treatment. It is accordingly requested that the Examiner reconsider and withdrawn this rejection of the claims.

II. Claims 5-10 have been rejected as being unpatentable over Morgan *et al.* (US 2003/0064988A1) under 35 USC 103(a) by the Examiner. It is the Examiner's contention that it would have been obvious to one of ordinary skill in the art to employ the (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol for the treatment of anxiety disorders because Morgan *et al.* (US 2003/0064988A1) teach that the compound is useful and effective for the treatment of an anxiety condition as set forth in numbered paragraph [0019] at page 2. The Examiner suggests that Morgan *et al.* (US 2003/0064988A1) teaches that the composition can be formulated with an optically pure form of the compound (or the salts and solvates thereof) at page 1, paragraph [0002]. The Examiner points out that Morgan *et al.* (US

2003/0064988A1) does not illustrate the administration of the compound for anxiety disorder. But according to the Examiner, it would be obvious to one of ordinary skill in the art to do so and that one would have been motivated to make such modification in order to achieve an expected benefit of treatment of anxiety disorders, generally taught by Morgan *et al.* (US 2003/0064988A1).

III. The Examiner has, likewise, rejected Claims 5-10 under 35 USC §103(a) as being unpatentable over Morgan *et al.* (US 2006/0189612A1) using the same reasoning employed above for Morgan *et al.* (US 2003/0064988A1).

Applicant's argument for both of these rejections (II and III) is as follows.

As amended, the application contains Claims 6, 9, and 10. Claim 6 relates to the treatment of "mixed anxiety-depressive disorder" as defined in the instant specification at paragraph [0021]. Morgan *et al.* (US 2003/0064988A1) and Morgan *et al.* (US 2006/0189612A1) do not teach the use of applicant's claimed compound for the treatment of mixed anxiety-depressive disorder. Neither does Morgan *et al.* (US 2003/0064988A1) or (US 2006/0189612A1) teach the use of applicant's claimed compound for the treatment of an anxiety condition as alleged by the Examiner. Paragraph [0019] in Morgan *et al.* (US 2003/0064988A1) or Morgan *et al.* (US 2006/0189612A1), respectively, defines "method of treating depression" by specifying particular types of depression followed by the following sentence. "In such treatments, accompanying treatment (alleviation) of *depression-related anxiety symptoms* is also contemplated." Thus, there is disclosed a treatment of a patient principally diagnosed with depression. There is not disclosed the treatment of a patient principally suffering from or diagnosed with an anxiety disorder as suggested by the Examiner. Depression-related anxiety symptoms is not the same disease/condition as anxiety disorders as asserted by the Examiner. Nor is it the same disease/condition as mixed anxiety-depressive disorder as set forth in Claim 6 of the present application. Accordingly, these rejections of Claim 6 should be reconsidered and withdrawn by the Examiner.

IV. Claims 5-10 have been rejected under 35 USC §103(a) as being unpatentable over Ascher *et al.* (US 2003/0032643A1). Again, the Examiner asserts that Ascher *et al.* teaches: (1) the use of the claimed compound for the *treatment of anxiety* and that the compound is useful and effective for the treatment of *anxiety*

condition. Therefore, according to the Examiner one would have been motivated by the disclosure in Ascher *et al.* to administer the claimed compound for *anxiety disorder*. [Emphasis added.]

Applicant's argument for this rejection is as follows.

As amended, the application contains Claims 6, 9, and 10. Claim 6 relates to the treatment of "mixed anxiety-depressive disorder" as defined in the instant specification at paragraph [0020]. Ascher *et al.* discloses the use of the compound for "treatment of seasonal affective disorder." (See Ascher *et al.* at page 2, paragraph [0020].) That is, according to Ascher *et al.*, the compound is used to treat an individual diagnosed as having seasonal affective disorder (SAD). The last sentence in the Ascher *et al.* paragraph [0020] reads "The symptoms of SAD usually recur regularly each fall or winter and can include a number of the following: change in appetite, change in weight, sleep problems (including a desire to oversleep, difficulty staying awake, disturbed sleep, early morning waking), lethargy, decreased energy level, leaden paralysis, difficulty concentrating, depression (feelings of misery, guilt, loss of self-esteem, hopelessness, apathy), social interaction problems (irritability, desire to avoid social contact, increased fear of social rejection, anxiety (tension, inability to tolerate stress), loss of libido, and mood changes." Ascher *et al.* does not disclose the treatment of a patient principally suffering from or diagnosed with an anxiety disorder as suggested by the Examiner. SAD is not the same disease/condition as anxiety disorder as asserted by the Examiner. Nor is SAD the same disease/condition as mixed anxiety-depressive disorder as set forth in Claim 6 of the present application. Accordingly, this rejection of Claim 6 should be reconsidered and withdrawn by the Examiner.

In summary, none of the cited documents, alone or combined, disclose a method of treatment for mixed anxiety-depressive disorder as set forth in Claim 6. As discussed in the application *in suit* (page 4, line 42 to page 5, line 11), mixed anxiety-depressive disorder is a disorder diagnostically distinct from depressive disorder, SAD, or anxiety disorder. The Examiner has used unallowable hindsight to make a perceived link to the treatment of the disorder now claimed (*i.e.*, mixed anxiety-depressive disorder) with those diseases/conditions disclosed in the cited documents, but without a disclosure in such documents pointing to this link. For

these reasons, it is submitted that Claims 6, 9, and 10 are not obvious in view of the disclosures of the cited documents either alone or in any combination.

Applicants believe the present claims are in condition for allowance and such action is respectfully requested.

Should any other fees be deemed necessary to effect the timely filing of this paper, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 07-1392.

If the Examiner has any outstanding issues with the pending claims, the Examiner is encouraged to telephone the undersigned at (919) 483-1577 for expeditious handling.

Respectfully submitted,

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